

**Title:** Why is it so difficult to integrate ethics in Health Technology Assessment (HTA)? The epistemological viewpoint

**Authors:** Refolo P<sup>1</sup>, Sacchini D<sup>1</sup>, Brereton L<sup>3</sup>, Gerhardus A<sup>4</sup>, Hofmann B<sup>2</sup>, Lysdahl KB<sup>2</sup>, Mozygemba K<sup>4</sup>, Oortwijn W<sup>5</sup>, Tummers M<sup>6</sup>, van der Wilt GJ<sup>7</sup>, Wahlster P<sup>4</sup>, Spagnolo AG<sup>1</sup>

1 Institute of Bioethics, “A. Gemelli” School of Medicine, Università Cattolica del Sacro Cuore, Rome, Italy

2 Centre for Medical Ethics, University of Oslo, Oslo, Norway

3 SchARR, University of Sheffield, Sheffield, United Kingdom

4 Department of Health Services Research, Institute of Public Health and Nursing Research, and Health Sciences, University of Bremen, Bremen, Germany

5 ECORYS Netherlands BV, Rotterdam, the Netherlands

6 Radboud Institute for Health Sciences, Radboud University Medical Centre, Nijmegen, the Netherlands

7 Donders Institute for Brain, Cognition and Behavior, Radboud University Medical Centre, Nijmegen, the Netherlands; Athena Institute for Innovation in the Health and Life Sciences, VU University Amsterdam, Amsterdam, the Netherlands

**Short title:** Ethics and HTA

**Correspondence:** Dario Sacchini, Institute of Bioethics, “A. Gemelli” School of Medicine, Università Cattolica del Sacro Cuore, Largo Francesco Vito 1, 00168 Rome, Italy. Tel.: +39.06.3015.4960; Fax: +39.06.3051149; E-mail: dsacchini@rm.unicatt.it

### **Abstract:**

Ethics has been identified as a key element in Health Technology Assessment (HTA) since its conception. However, ethical issues are still not frequently addressed explicitly in HTA. Several valuable reasons have been identified.

The basis of the article is the claim that ethics is often not part of HTA for “epistemological reasons”. Hence, the main aim of the contribution is to explore in more details and emphasize them by using the fact/value dichotomy.

Our conclusion is that current HTA configuration is dominantly based on the comparison among objective and empirically testable “facts”, whilst ethics is not empirically testable. In this sense, there is a sort of “epistemological gap”, which can explain why it is so difficult to integrate ethics in HTA. We suggest that the epistemological differences among the various domains of HTA are addressed more explicitly.

**Keywords:** ethics, Health Technology Assessment, epistemology, integration.

## Introduction

From the conception of Health Technology Assessment (HTA) in the 1970s, it has been argued that ethics is a constitutive part of HTA. Ethics within an HTA aims at analysing the ethical issues raised by the consequences of implementing/not implementing a health technology [1-4].

Early, as well as more recent definitions of HTA include ethics. For instance, in 1985, the U.S. Institute of Medicine defined HTA as “any process of examining and reporting properties of a medical technology used in health care, such as safety, efficacy, feasibility, and indications for use, cost, and cost-effectiveness, as well as social, economic, and *ethics* consequences, whether intended or unintended” [5].

The European network for Health Technology Assessment (EUnetHTA) defines HTA as: “a multidisciplinary process that summarises information about the medical, social, economic and *ethical* issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value” [6].

Indeed, over the last 40 years, ethics has rarely been part of HTA work and ethical issues are still not frequently addressed explicitly in HTA. Some studies can confirm this argument: a 2000 study by Lehoux and Blume of the 1999 International Society of Technology Assessment in Health Care CD-ROM database of abstracts presented at the Annual Meetings (1994-1998) and all abstracts of papers published in the International Journal of Technology Assessment in Health Care (1985-1999) found that from a total of 2.906 records, only 19 records contained “ethical” in their title (0,7%) [7]. An analysis of 680 HTA reports produced by six Canadian agencies between 1997 and 2006 showed that only 17% addressed ethical issues [8]. In 2003, the Deutsches Institut für Medizinische Dokumentation und Information (DIMDI) arrived at similar conclusions analysing “short assessments on medical technologies” published worldwide (n = 282): only 25 reports (9%) described ethical issues [9].

A 2007 survey showed that only 5% of 223 HTA reports published between 2003 and 2006 from nine different agencies (five in Canada, two in the UK, one in Denmark and one in the USA) considered ethical, social and organizational issues, in addition to clinical and economic evaluations [10].

The above trend can be considered as unexpected for at least four reasons: 1. Ethics is part of HTA definitions. 2. HTA has a moral aim (to improve health and care for people); 3. HTA is evaluative; 4. Technology is value laden and confronts us with moral problems which need to be

addressed is supported by a large part of contemporary philosophy (Horkheimer, Adorno, Heidegger, Jonas, Gehlen, Hottois just to mention a very few examples). Consequently, it is quite strange that researchers have not embarked on this activity, i.e. the ethical assessment of health technologies, especially as ethical and social issues are at the core of HTA's big brother, Parliamentary Technology Assessment. It is particularly surprising that Bioethics, whose future itself is currently debated, seems unable to take on this task.

Why does it happen so rarely that ethics is integrated in HTA? At first glance, the reason seems not to be "methodological", i.e. related to "how" this type of investigation is performed. Over the years a wide range of approaches have been suggested to address ethical aspects of health technologies. A recent systematic review [11] has identified 43 conceptual frameworks or practical guidelines for addressing ethical issues in HTA, so some authors [12,13] have asked whether there are more methods than applications.

Several reasons why ethics is not a part of HTA have been identified.

According to ten Have, ethical analysis is rarely incorporated in HTA studies for two reasons: technology would often be regarded as a "value-neutral" tool; at the same time, bioethics would be dominated by an "engineering" model of moral reasoning [14].

Hofmann has identified ten arguments for why ethics should be part of HTA [13] and has identified the following list of reasons why ethics may not be integrated in HTA: "A) Ethicists are professional strangers in HTA, i.e., the "goals, methods, models, and modes of rationality of HTA and ethics are categorically dissimilar". B) A common agreed methodology for integrating ethics is lacking. Ethics methodology appears to be C) deficient, D) insufficient, or E) unsuitable. F) Integrating ethics in HTA is neither efficient nor needed for successful HTA. G) Most moral issues are general, and are not specific to a given technology. H) All relevant ethical issues can be handled within other frameworks, e.g., within economics. I) Ethics can undermine or burst the foundation of HTA" [15].

The reasons discussed by Hofmann are mainly practical and discussed from within the HTA perspective. Although epistemic reasons are mentioned, Hofmann does not elaborate on this.

Therefore, the hypothesis to be investigated in this article is that ethics is not a part of HTA for "epistemological reasons". Our aim is to explore them by using the fact/value dichotomy. Before we do that, we would like to try to explain in more detail what it means to integrate ethical inquiry in HTA.

## **HTA & ethics. What does it mean to integrate ethics in HTA?**

HTA is a multidisciplinary process that summarises information about the short- and the long-term consequences of implementing/not implementing a health technology. The purpose of HTA is to support the process of decision-making in health care by providing the “best” information. In this respect, HTA has been compared to a “bridge” between the world of research and the world of decision-making [16].

In order to achieve this, HTA is committed to the activity of collecting and analysing “evidence” from research in a systematic and reproducible way and to make it accessible and usable for decision-making purposes by means of “assessment” reports.

“Assessment” is generally defined as the action of evaluating relevant aspects of the health technology to form a basis for decision making. It is almost always comparative: the health technology under review is evaluated against some specified standard of performance or other products and treatments. For instance, assessment of In Vitro Fertilization and Embryo Transfer (IVF-ET) safety can be performed by comparing its safety profile with the safety profile of another reproductive technology (e.g., with Intra-Cytoplasmic Sperm Injection, ICSI).

“Assessment” differs from “appraisal”, which generally implies some form of recommendation (prescriptive level) about the implementation/non implementation of the technology based on the assessment [17]. Such a recommendation can lead to several concrete actions: encouraging, discouraging or even prohibiting implementation, reimbursing, funding, disinvesting, etc. Some HTA-agencies are restricted to assessments of the technology only and do not make recommendations about implementation/not implementation in the healthcare system, while others perform both assessment and appraisal.

What does it mean to perform an ethical assessment? What does it mean exactly to integrate ethics in HTA? What does it mean “to support” the process of decision-making by providing the “best information” about the ethical issues of implementing/not implementing a health technology?

There are many answers to these questions [4].

According to EUnetHTA, the ethical domain involves “an understanding of the consequences of implementing or not implementing a health care technology in two respects: with regard to the prevailing societal values and with regard to the norms and values that the technology itself constructs when it is put into use” [18]. In addition, the domain also covers “moral and ethical issues related to the consequences of performing the health technology

assessment (HTA)” [18]. The HTA process itself can, in fact, raise ethical issues [2]. These are, for example, issues about the ethical consequences of the choice of endpoints or of comparators, and whether there are any ethical issues in the economic evaluation [2,19].

The ethical analyses in HTA vary according to the distinction between assessment and appraisal, e.g., sometimes ethical analyses consist in: 1. a “simple” list of ethical issues, which have to be identified, described, and addressed (the most widely used modality); or, in a more complex way, 2. moral judgements (e.g., the use of the technology X is morally good/bad or licit/illicit).

With reference to IVF-ET, it is one thing to identify, describe, and address ethical issues connected to its implementation (such as risk of ovarian hyperstimulation syndrome in women, embryo freezing, pre-implantation diagnosis, etc.) and another thing to judge whether its implementation is morally good/bad or licit/illicit as a whole.

In a certain sense, also the “configuration” of the approaches for the ethical analysis in HTA reflect this “dichotomy”: some of them (e.g., the *HTA Core Model* [18] or the *Socratic approach* [19]) consist of “conceptual frameworks” (which are often characterized by both a set of questions and wide literature search), whose aim is to identify the ethical issues in a clear and efficient manner. Others are represented by the well-known classic models of Moral Philosophy (e.g., Deontology, Utilitarianism, Casuistry, etc.), which are more useful to make morals judgements.

### **The Fact/Value dichotomy**

The difference in interpreting ethical analysis as well as the difficulty in integrating ethics in HTA can be due to epistemological reasons.

HTA encompasses domains which are “epistemologically heterogeneous”: some of them clearly belong to the natural sciences (e.g., safety, effectiveness), others humanistic (e.g. ethical, socio-cultural and legal domains) [20]. The former follow methods from the natural sciences and are empirically testable; the latter are dealing with meaning and are not empirically testable.

For instance, the safety domain is based on “verifiable facts” (e.g., that ovarian hyperstimulation treatment can cause bleeding is a verifiable fact) – even though “new facts” could disprove previously tested facts. On the other hand moral statements and ethical assessments are not empirically testable (the morality of IVF-ET cannot be established through observations), although ethical arguments and assessments may include [21-24] empirical premises.

The relationship between sciences and humanities or, more specifically, between the natural sciences and ethics has been one of the most debated topic in modern philosophy and has been addressed in many ways.

One debate consists of wondering whether it would be possible “to draw” moral norms from the knowledge or norms of nature; another discussion focuses on studying the relationship between descriptive propositions (e.g., the moon is spherical) and normative propositions (e.g., killing is despicable); a further debate fundamentally considers whether ethics is an authentic form of knowledge [25].

At the centre of much of this debate there has been a famous passage from the Scottish philosopher David Hume (1711-1776): “In every system of morality, which I have hitherto met with, I have always remarked, that the author proceeds for some time in the ordinary ways of reasoning, and establishes the being of a God, or makes observations concerning human affairs; when all of a sudden I am surprised to find, that instead of the usual copulations of propositions, is, and is not, I meet with no proposition that is not connected with an ought, or an ought not. This change is imperceptible; but is however, of the last consequence. For as this ought, or ought not, expresses some new relation or affirmation, 'tis necessary that it should be observed and explained; and at the same time that a reason should be given, for what seems altogether inconceivable, how this new relation can be a deduction from others, which are entirely different from it. But as authors do not commonly use this precaution, I shall presume to recommend it to the readers; and am persuaded, that this small attention would subvert all the vulgar systems of morality, and let us see, that the distinction of vice and virtue is not founded merely on the relations of objects, nor is perceived by reason” [26].

The passage is also known as “Hume’s law” or “Hume’s guillotine” and has been interpreted in many ways. In short, it states that you cannot logically derive an “ought” from an “is”, that is, you cannot derive “norms” from “facts” – there is no logical bridge between fact and value.

A similar argument has been defended by the English philosopher George Edward Moore (1873-1958). In his *Principia ethica*, he argued against any identification of moral properties with natural properties. In particular, he argued against what he called the “naturalistic fallacy” in ethics, by which he meant any attempt to define the word “good” in terms of some natural quality.

The German sociologist Max Weber (1864-1920) arrived at similar conclusions too. He made a strict distinction between “statements of facts” (describing reality) and “statements of value” (relating to an ideal). The former were considered to be objective and the latter subjective. On this basis, he argued that science, as the realm of facts, has to be considered strictly separated from the realm of values, i.e., ethics, aesthetics, and politics.

Despite some differences in terminology, all the afore mentioned authors made a clear distinction between facts and values, and repudiated any attempt to derive moral values from facts.

The same argument has been defended by the Neo-positivism (also called Logical Positivism or Logical Empiricism), an important philosophical movement of the early 1900s, whose radical fringes ended up arguing even that normative propositions are meaningless.

20th Century Neo-positivism can be considered a more up to date version of Positivism of the 19th Century. The new positivists maintained the radical empiricism from the old movement, the attention given to the development of the sciences, and the clear aversion to metaphysics.

Its representatives gave a fundamental role to the logical techniques (which explains the addition of the adjective logical to Positivism) elaborated by Gottlob Frege, Bertrand Russell and Alfred North Whitehead at the beginning of the 20th Century. Such techniques had tried to create “artificial” and “neutral” languages capable of eliminating the unavoidable ambiguity present in everyday language.

The aim of Neo-positivism was to establish a “scientific philosophy” which as far as possible would respect the criteria of rigor and exactitude. It can be interpreted as a program of radical “re-foundation” of the knowledge upon empirical bases, which would have had to lead to the elaboration of a “unified language” for the whole science based on the model of physics.

The assumption on which the whole philosophical conception of Neo-positivism was based is the well-known “theory of verification,” according to which a proposition is “cognitively meaningful” only if some finite procedure conclusively determines its truth. Metaphysics, ontology, as well as ethics fail this criterion, and therefore, they were considered to be cognitively meaningless. In this way, Neo-Positivism celebrated a sort of “divorce” of science from ethics.

However, from the 60s both Hume’s law and Neo-positivism lost appeal.

In this context, the “Philosophical hermeneutics” initiated by Martin Heidegger and developed by Hans-Georg Gadamer in his *Truth and Method* came to play a fundamental role. In essence, Gadamer claimed that understanding is not fixed but rather changing and indicating new

perspectives, because a certain “prejudice” is always present. Hence, understanding is always personal, subjective and never “disinterested”.

This assumption had an impact on the methodological presuppositions on which modern science was based. According to the new viewpoint, there can be no universal standpoint from which “objective knowledge” can be achieved, and all understanding – also scientific understanding – has to be considered as “contextual” and “historical”.

Another important role has been played by the German philosopher Karl-Otto Apel (1922-). He pointed out that moral language analysis always requires a criterion to distinguish moral language from any other form of language. This helped to support the thesis that existence of merely descriptive propositions is an illusion and that it is impossible to separate normative dimension from descriptive analysis.

Importantly, the American philosopher Hilary Putnam (1926-) has recently traced the “collapse of the fact/value dichotomy”. According to him, there is a distinction to be made, useful in some contexts, between statements of fact and statements of value, especially of ethical value. Nevertheless, a strict dichotomy between fact and value would be indefensible because on the one side normative (e.g., ethical and aesthetic) judgments have always a factual basis, and on the other side scientific judgments encompass normative elements. As a consequence, science cannot be considered as “value-free” since “science itself presupposes values which are in the same boat as ethical values with respect to objectivity” [27].

These and others reflections have reduced the significance of the fact/value dichotomy. At the same time, there has been an increased consciousness that technical-instrumental rationality cannot be considered as the only form of knowledge. So, the monism of the neopositivistic epistemology has entered a crisis, and a sort of “epistemological pluralism” has arisen, thus opening new research perspectives.

There are several “cultural signs” of this epistemological change. First of all, the rehabilitation of the Aristotelian practical philosophy [28]; secondly, the studies on the “normative tasks” connected to rationality by Discourse Ethics (particularly, by Jürgen Habermas and Karl-Otto Apel) [29]; thirdly, the birth of some forms of applied ethics (e.g., clinical ethics, business ethics, organizational ethics, etc.); finally, the incorporation of Humanities into medical education. More generally, we could say that ethics has started to be considered as a “more integrative part” of the scientific discourse. This can clearly be seen in (Parliamentary) Technology Assessment, which is



much more based on the social sciences than HTA, where the value-ladenness of technology and “empirical facts” is explicitly addressed.

## **Discussion**

The integration of ethics in HTA can be considered as part of this trend. From a cultural point of view, it can be interpreted as an attempt to overcome the neopositivistic epistemology, which was only interested in technical and empirically testable issues.

Why it is so difficult to integrate ethics in HTA seems now be clearer and easier to explain: ethics meets the same difficulties and “prejudices” that itself meets whenever it attempts to access to the scientific discourse.

To complicate matters, probably HTA owes much of its success to empirical testing itself. One of the main strengths of HTA is its great “ability” to provide empirical evidence in order to support the decision making. It is well known that HTA relies heavily on Evidence-based medicine (EBM), which is a strictly empirical approach. For instance, safety assessment is generally performed by means of observation or experimentation, which allow the acquisition of “objective information”.

On the contrary, ethics fails to provide this type of “evidence”, that is, it cannot be empirically tested. In this sense, the morality of IVF-ET cannot be established through observations.

However, the fact is that such epistemological difference is not well highlighted in the definition of HTA. All the domains appear to be on the same level. Hence, some – above all people not expert in ethics – might think that the ethical domain is capable of providing “empirical evidence” and that it can be treated like, for example, the safety domain. As the operation of providing this type of evidence fails, then ethical analyses end up being considered as ineffective, inconclusive or unnecessary. It’s almost like if all the old neopositivistic prejudices against any form of knowledge which cannot be empirically testable resurface.

To sum up, current HTA configuration is dominantly based on the comparison among objective and empirically testable “facts”, whilst ethics is not empirically testable. Therefore, there is a sort of “epistemological gap”, which can explain why it is so difficult to integrate ethics in HTA.

Frameworks identifying moral issues with implementing health technologies are directed at highlighting value issues in order for the legitimate decision makers to make the decisions about health technologies. Classic methods from moral philosophy (such as consequentialism,

deontology, casuistry etc) are more oriented at providing recommendations. The former therefore appears to support a fact-generating paradigm, while the latter appears to support a meaning or decision generating paradigm. However, although this appears to underscore the “two cultures” described above, it more correctly is based on the distinction between assessment and appraisal, described at the outset of this article. In assessment decisions about moral issues are not made by “moral experts,” i.e., ethicists, but by persons with legitimate decision making capacity in the same manner as decisions about the appropriate level of effectiveness and efficiency is not made by medical and economic experts.

## **Conclusion**

From an epistemological point of view, the regard for the ethical consequences of implementing/not implementing a health technology can be considered as part of a more general cultural process of rehabilitation of ethics into the scientific discourse.

However, HTA encompasses branches of knowledge, which are heterogeneous from an epistemological standpoint, but it owes much of its success to those forms of knowledge, which can be empirically testable.

In our opinion, greater emphasis should be given to the notion both that ethical analysis “works” on a different level and that its findings have a different “meaning”. As a result we therefore recommend that the epistemological differences among the various domains of HTA are addressed more explicitly.

In this way, perhaps, this sort of “method dispute” (*Methodenstreit*) for integrating ethics in HTA will be mitigated and applications – which represent the “true heart” of the integration – could be finally enhanced.

## **Competing interests**

The authors report no competing interests.

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